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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,037	11/25/2005	Paul Heeres	294-219 PC'D/US	1310
23869 7590 06/21/2010 HOFFMANN & BARON, LLP 6900 JERICHO TURNPIKE SYOSSET, NY 11791				
EXAMINER ROBINSON, KEITH O'NEAL				
ART UNIT 1638		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/537,037

Applicant(s)

HEERES ET AL.

Examiner

KEITH O. ROBINSON

Art Unit

1638

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 February 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10, 12 and 15-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10, 12 and 15-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 June 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB06)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notes of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 18, 2010 has been entered.

Applicant's cancellation of claims 1-9, 11, 13 and 14 and amendment of claims 10, 12, 15-17, 23 and 24, filed February 18, 2010, have been received and entered in full.

Claims 10, 12 and 15-24 are under examination.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 is dependent upon a cancelled claim; thus, Applicant fails to particularly point out and distinctly claim the claimed invention.

Claim 23 cites the word "providing" in line 2. The word "providing" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Thus, it is unclear what are the metes and bounds regarding "providing".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 10, 12 and 15-22 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobsen et al (Euphytica 44: 43-48, 1989), in view of Jacobsen et al

(Euphytica 53: 247-253, 1991), in view of Poehlman et al (Breeding Potato, *In* Breeding Field Crops, Chapter 21, pages 419-433, 1995).

The claims read on a method comprising (a) crossing a first parent potato plant having at least one *amf*-allele with a second parent potato plant to produce progeny; (b) selecting and testing said progeny for the presence of at least one *amf*-allele and for protein content; wherein said testing for protein content is performed by determining protein content of tubers or root caps of said progeny; and (c) selecting progeny having at least one *amf*-allele with a protein content higher than detected in said first parent or said second parent (claims 10 and 16).

Limitations include selecting progeny homozygous for the *amf*-allele (claims 12, 15 and 17); wherein the protein content of tubers of the selected progeny is at least 0.9% m/m, 1.2% m/m, and 1.5% m/m (claims 18, 19 and 20, respectively); wherein coagulating protein versus starch ratio of the selected progeny is at least 45 kg/ton and 90 kg/ton (claims 21 and 22, respectively).

Jacobsen et al (1989) teach a method for breeding and selecting a potato comprising crossing a first parent potato with at least one *amf*-allele with a second parent potato without an *amf*-allele. See, for example, page 44, 2nd column, last paragraph to page 45, 1st column where it teaches "[c]rosses have been made with four...doubled shoots of the *amf*-mutant...and with the amylose containing diploids 87.007 and 87.0008". Also see, for example, page 45, Table 1 where it teaches pollination of *amf*-mutant 86.040 with amylose containing diploid plants.

Jacobsen et al (1989) teach selecting progeny by testing said progeny for the presence of at least one *amf*-allele. See, for example, page 45, last paragraph to page 46, 1st column where it teaches analyzing plantlets for starch granule composition in columella cells. In addition, Jacobsen et al (1991) teach selecting progeny for the presence of at least one *amf*-allele. See, for example, page 249, 2nd column, last paragraph to page 250, 1st column, lines 1-13 where it teaches selection of amylose free genotypes.

Jacobsen et al (1989) teach selecting progeny homozygous for the *amf*-gene. See, for example, page 47, 1st column, last paragraph where it teaches that the mutant *amf*-character in potato plants is recessive and monogenic and see Table 3 where plants having the *amf*-character were selected.

Jacobsen et al (1989) do not teach selecting progeny having at least one *amf*-allele with a protein content higher than detected in said first parent or said second parent.

Jacobsen et al (1989) do not teach wherein the protein content of tubers of the selected progeny is at least 0.9% m/m, 1.2% m/m, and 1.5% m/m.

Jacobsen et al (1989) do not teach wherein coagulating protein versus starch ratio of the selected progeny is at least 45 kg/ton and 90 kg/ton.

The references are silent with regard to the protein content of tubers of the selected progeny is at least 0.9% m/m, 1.2% m/m, and 1.5% m/m; however, Poehlman et al teach the importance for breeding for protein content and it would have been

obvious to one of ordinary skill in the art that the protein content of the selected potato plant would depend upon the goals of the individual breeder.

The references are silent with regard to coagulating protein versus starch ratio of the selected progeny is at least 45 kg/ton and 90 kg/ton; however, it would have been obvious to one of ordinary skill in the art to select potato plants with a high protein versus starch ratio based on the teachings of Poehlman et al with regard to the importance of breeding for protein content.

One of ordinary skill in the art would have been motivated to combine the cited references because Jacobsen et al (1991) teach that potato is the raw material for industrial production of starch and that starch producers prefer potato cultivars with different ratios of amylopectin and amylose (see page 247, 1st column, 1st paragraph) and Poehlman et al teach the importance of breeding for protein in potato; thus, one of ordinary skill would have been motivated to combined the cited references to produce a potato plant that is both amylose free and high in protein.

Claims 23 and 24 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobsen et al (Euphytica 44: 43-48, 1989), in view of Jacobsen et al (Euphytica 53: 247-253, 1991), in view of Poehlman et al (Breeding Potato, *In* Breeding Field Crops, Chapter 21, pages 419-433, 1995) as applied to claims 10, 12 and 15-22 above, and further in view of Farran et al (Transgenic Research 11: 337-346, 2002).

The claims read on the method of claim 16, further comprising providing said selected progeny with a gene encoding a heterologous protein, wherein the

heterologous protein is selected from the group consisting of DHPS, PMC, vicilin, SCR1, Fcor2, TLRP, multicystatine, yZein, 10kDa Zein, 2S albumin, TIP13, PTGRP, PA1b, SE60 and PCP1.

Jacobsen et al (1989), in view of Jacobsen et al (1991), in view of Poehlman et al teach a method comprising (a) crossing a first parent potato plant having at least one *amf*-allele with a second parent potato plant to produce progeny; (b) selecting and testing said progeny for the presence of at least one *amf*-allele and for protein content; wherein said testing for protein content is performed by determining protein content of tubers or root caps of said progeny; and (c) selecting progeny having at least one *amf*-allele with a protein content higher than detected in said first parent or said second parent.

Jacobsen et al (1989), Jacobsen (1991) and Poehlman et al do not teach providing selected progeny with a gene encoding a heterologous protein, wherein the heterologous protein is selected from the group consisting of DHPS, PMC, vicilin, SCR1, Fcor2, TLRP, multicystatine, yZein, 10kDa Zein, 2S albumin, TIP13, PTGRP, PA1b, SE60 and PCP1.

Farran et al teach providing potato plants with a gene encoding a heterologous protein. See, for example, page 338, 2nd column, last paragraph to page 339, 1st column, 2nd paragraph where it teaches providing potato plants with human serum albumin. One of ordinary skill in the art would have understood that other heterologous proteins can also be used in the method taught by Farran et al because they teach,

"Potato tubers may be used, by applying this technology, to produce other heterologous proteins of interest...".

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the method of Jacobsen (1989) as taught by Jacobsen (1989) in view of Jacobsen (1991) in view of Poehlman to use heterologous protein as described in Farran et al. One of ordinary skill in the art would have been motivated to do so because Farran et al teach that potato would be an organ of choice for production of serum protein (see page 337, 2nd column, last paragraph) and Poehlman et al teach the importance of breeding for protein content in potatoes, as discussed above.

Response to Arguments

Applicant argues that the Examiner does not point out why a skilled artisan would expect that an allele relating to amylose-free starch would increase protein storage capacity (see page 6, 4th and 5th paragraphs of 'Remarks' filed February 18, 2010).

This is not persuasive. It is not necessary for a skilled artisan to expect that an allele relating to amylose-free starch would increase protein storage capacity when breeding and selecting for a potato having increased protein content because the claimed method claims a cross between a parent potato having at least one *amf*-allele with any parent potato to produce progeny and selecting for progeny having both an *amf*-allele and protein. Thus, the second parent can be any potato plant, including potato plants with high protein content.

One of ordinary skill in the art would have been motivated to combine the cited references because the references combined teach the importance of amylose free starch and protein content in potato. Thus, it would have been obvious to one of ordinary skill in the art to combine these desirable characteristics into a potato plant by crossing and selecting potato plants.

Conclusion

No claims are allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KEITH O. ROBINSON whose telephone number is (571)272-2918. The examiner can normally be reached Monday – Friday, 8:00 a.m. - 4:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Keith O. Robinson

/Anne R Kubelik/
Primary Examiner, Art Unit 1638